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D.G.

EXAMINER K

NUTTER, N	PAPER NUMBER
	9

OMRI M. BEHR
325 PIERSON AVENUE
EDISON, NJ 08837

DATE MAILED:

08/17/92

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☐ This application has been examined ☒ Responsive to communication filed on 24 June 1992 ☒ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), ____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☒ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice re Patent Drawing, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, Form PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____

Part II SUMMARY OF ACTION

1. ☒ Claims 1 - 11 are pending in the application.
   Of the above, claims 4 - 7 are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 1 - 3 and 8 - 11 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable. ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed on _____, has been ☐ approved. ☐ disapproved (see explanation).
12. ☒ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☒ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 1-3 and 8-11 are rejected under 35 U.S.C. § 103 as being unpatentable over Nitsch et al. taken with Staley Manufacturing (GB 935,339) and Morishita Pharmaceutical (GB 1 395 777).

The reference to Nitsch et al. teaches the production of an hydroxyethyl starch useful as a plasma expander which may include starch derivatives having molecular weights in the range of, preferably, 200,000 to 450,000 Daltons, which lies within the range recited by applicants in the instant claims. Note column 3 (lines 21-24). At column 3 (lines 25-28) for a molar substitution of 0.1 to 0.8. The reference teaches hydrolysis of amylopectin-rich starch followed by hydroxyethylation. Note column 2 (lines 38-43) which teaches hydrolytic decomposition, to

adjust the starch/product to an acceptable molecular weight, as set out at column 3 (lines 21-24). Note column 2 (lines 44 et seq.) which teaches the employment of analkylene oxide in the presence of alkali for the etherification. Note the paragraph bridging column 2 to column 3 for the purification of the product. Finally, note the conversion step of producing a dry powder by spray drying at column 3 (lines 8-20). The process steps are deemed to be conventional.

The reference to Staley Manufacturing (GB 935,339) teaches the production of an hydroxyethyl starch derivative which has a molar substitution greater than 0.15 at page 1, (lines 52-60). The patent further teaches that specific molar amounts of etherification agent must be present to achieve specific molar substitution, that is, that the degrees of molar substitution is dependent and manipulable relative to the amounts of etherification agent employed at page 3 (lines 12-32). Further, note Tables I and II at pages 6 and 7.

The British patent to Morishita Pharmaceutical teaches the production of "a hydroxyethyl starch having a molar ratio between the resulting hydroxyl group at the 2-position and those at the 6-position of 0.5 to 2.0 (5 to 20)" at page 1 (lines 6-8). Further, at page 2 (lines 21-28) the patent teaches the manipulation of the ratio as being dependent on varying the amounts of alkali relative to the amount of hydrolyzed starch.

The molar ratio of C_2 to C_6 disclosed by the reference embraces that of the instant claims.

The primary reference to Nitsch et al. teaches the production of an hydroxyethyl starch from hydrolyzed amylopectin-rich starch essentially as recited in the instant claims, except for the specific molar substitution and C_2 to C_6 ratio recited. The British patent to Staley, also drawn to production of an hydroxyethyl starch teaches that it is known how to manipulate the molar substitution of hydroxyethyl starch. Finally, the British patent to Morishita Pharmaceutical, likewise drawn to production of an hydroxyethyl starch, teaches that it is known how to manipulate the C_2 to C_6 ratio of substitution. All references are drawn to hydroxyethyl starch production. The compounds of the claims are employed in the identical capacities as those of Nitsch et al. Thus, the production of an hydroxyethyl starch plasma extender as recited in the instant claims would have been obvious from the teachings of the references to a practitioner having an ordinary skill in the art at the time the invention was made. No surprising or unexpected results have been shown on the record.

Applicant's arguments filed 24 June 1992 have been fully considered but they are not deemed to be persuasive.

With regards the restriction requirement, the examiner urges that the process as claimed can be used to make other and

materially different products such as other starch ethers, depending upon choice of etherification agents which are well known in the etherification art such as propylene oxide, ethylene oxide, as disclosed in Nitsch et al. at column 2 (lines 44-57). The etherification art is replete with known etherification agents. Further, etherification of polysaccharides broadly, as agreed by applicants at page 2, first full paragraph, of the Response, Paper No. 8, is dependent upon the existence of an hydroxy group, of which polysaccharides, in general, possess by definition. Further, note the patents to Portnoy et al. and Eastman, cited only in this regard. Note the variety of etherification agents at column 1 (lines 51-58) of Portnoy et al. Note in Eastman at column 4 (lines 3-20) for a variety of agents which may be used to produce respectively different starch ethers. Simply put, the process as claimed can be used to make other and materially different products as is a required criterion for restriction in accordance with MPEP 806.05(f). Further, note the patent to Pope, cited only with regards the restriction requirement which shows broadly that the use of one polysaccharide over another for etherification is a matter of choice. Note column 2 (lines 9-17) which teaches the broad concept of etherification, i.e. "susceptible to hydroxyalkylation". Certainly, cellulose is one. Thus, the process again is deemed to be properly restrictable in accordance

with MPEP 806.05(f). Applicants have not shown anything different on the record.

Claims 8-11 are still deemed to be linking claims, however, the claims still are drawn to a product, albeit produced by the process recited.

This application contains claims 4-7 are drawn to an invention non-elected with traverse in Paper No. 4. A complete response to the final rejection must include cancellation of non-elected claims or other appropriate action (37 C.F.R. § 1.144) M.P.E.P. § 821.01.

Applicants' arguments are cased in language which would be indicative of a rejection under 35 USC 102, which is not the situation. The rejection is being made under 35 USC 103 over Nitsch et al. taken with Staley Manufacturing (GB 935,339) and Morishita Pharmaceutical (GB 1 395 777).

The references to Staley is relied upon solely to show the manipulation of the molar substitution of starch. To manipulate the molar substitution of the starch derivative would have been obvious to a practitioner. Thus, to manipulate the molar substitution by following the teachings of Staley would have been a mechanical modification to a practitioner at the time the invention was made.

Further, manipulation of the C_2 to C_6 ratio is shown by the British patent to Morishita Pharmaceutical as disclosed at page 2

(lines 21-28) thereof, by use of the "alkali as a reagent but not as a catalyst". The ratio set out by Morishita 0.5 to 2.0 of C_2 to C_6 is clearly within the ratio of 8 to 20 of the instantly claimed product at 5 to 20.

As regards the Declaration of Sommermeyer filed under 37 CFR 1.132, paper no. 5, the Declaration is drawn to the concept that "HES (500/03) plasma extender was substantially eliminated from the plasma of ..volunteers within from about three hundred sixty to four hundred eighty minutes (conclusion, paragraph no. 5, page 3 of the Declaration)". The Declaration is only drawn to establishing a particular inherent characteristic of the product recited in the instant claims. No comparative showing is made with products of the prior art or with products made using the teachings of the prior art. The Declaration is, as such, not deemed to be germane as to the rejection as set out in the previous Office action, Paper No. 6, or herein.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM

THE DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication should be directed to Nathan Nutter at telephone number (703) 308-2351.

Nutter:css
August 12, 1992
August 17, 1992

NATHAN M. NUTTER
PATENT EXAMINER
ART UNIT 153